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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/767,679 Filing Date: January 29, 2004

Appellant(s): SUBRAMANYAN ET AL.

Milton L. Honig Registration No. 28,617 For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed March 27, 2006 appealing from the Office action mailed January 18, 2006.

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(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

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(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

The Examiner notes that Appellants filed an Appeal Brief in U.S. Patent Application Serial No. 10/347,982 on March 22, 2006. While this co-pending application is not related as a continuation or parent of the instant application, the co-pending application does contain claims to cosmetic compositions with malonic acid salts, including claims reciting a ratio of the partially neutralized to fully neutralized malonic acid salts.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. In particular, the rejection of claims 1-3 and 5-11 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0224023 to Faryniarz et al. in view of U.S. Patent No. 6,180,121 to Guenin et al, and the rejection of claims 1-3 and 5-11 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Application Publication No. 2003/0224027 to Faryniarz et al., are being withdrawn under the provisions for common ownership as set forth by 35 U.S.C. 103(c).

The Faryniarz et al. references qualify as 103 type references under the provisions of 35 U.S.C. 102(e), and do not qualify under 35 U.S.C. 102(a) or (b), as the instant claims receive benefit of the filing date of the provisional application, and the filing date of the application is less than one year from the publication date of the

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references. Appellants indicated in the Appeal Brief that the inventors of the Faryniarz et al. reference and those of the instantly claimed invention "all had an obligation of assignment to the same entity at the time the present invention was made" (see page 11, second full paragraph, and paragraph bridging pages 11-12 of Appeal Brief.)

Accordingly, the Faryniarz et al. references are disqualified as prior art under the

provisions of 35 U.S.C. 103(c).

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,641,495 Jokura et al.

6-1997

6,180,121

Guenin et al.

1-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,641,495 to Jokura et al. in view of U.S. Patent No. 6,180,121 to Guenin et al.

Jokura et al. teaches a skin cosmetic causing little irritation and having an excellent moisturizing effect having (A) a ceramide or pseudoceramide, (B) a dicarboxylic acid, and (C) a salt of a dicarboxylic acid (see abstract, in particular.)

Jokura et al. teaches that the dicarboxylic acid and dicarboxylic acid can comprise malonic acid (see column 3, lines 30-50, in particular.) Jokura et al. also teaches that water, ethanol and/or water-soluble polyhydridic alcohols can be employed as a base (cosmetically acceptable carrier), and can be provided in an amount of from about 0.1 to about 90% by weight of the composition (see column 4, lines 16-34, in particular), which meets the limitation of being from "about" 1 to "about 99% by weight as recited in claim 1.

Jokura et al. teaches that the dicarboxylic acid and dicarboxylic acid salt have a percent by weight in the composition of from 0.01 to 20% (see column 3, lines 53-56, in particular), and that the ratio of the carboxylic acid to the dicarboxylic acid salt in the composition can be from 1/9 to 9/1 (see column 3, lines 55-60, in particular.)

Accordingly, Jokura et al. meets the limitation of comprising a salt of malonic acid in from "about" 0.0001 to "about" 30% by weight of the composition, as recited in claim 1.

Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the percent content of the malonic acid salt in the composition, in accordance with the guidelines set forth by Jokura et al, to provide a skin composition having desired moisturizing effects and little skin irritation. It is noted that "[W]here the general conditions of a claim are disclosed in

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the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Jokura et al. also teaches that the composition can further comprise other components that are commonly used in cosmetic, such as perfumes (see column 5, lines 20-34, in particular.)

Jokura et al. does not specifically teach the composition comprising the percent weight of fragrance having the percent weight of terpenoid as recited in claim 1.

Guenin et al. teaches fragrance enhancing compositions for cosmetic products (see abstract, in particular.) Guenin et al. teaches that fragrance composition can be combined into the composition in an amount of from 1.8 to 32.5% by weight, and teaches that the exemplary Deo-KeyTM fragrance compositions can combined in an amount of about 3% by weight (see column 8, line 63 through column 7, line 7, in particular), which meets the limitation of the fragrance percent content as recited in claim 1. Guenin et al. teaches that the fragrance composition can be made by combining at least three components from a group of listed fragrances that includes terpenoids such as d-limonene, citral and geraniol, and terpenoid containing fragrances such as Iso Methyl Cedryl Ketone A and Pelargonyl (see column 2, line 20 through column 3, line 35, in particular.) Guenin et al. furthermore exemplifies Deo-KeyTM fragrance compositions comprising a terpenoid in the recited percent by weight of the

fragrance composition, such as for example Orange Oil Morroco (limonene) in a percent by weight of 2.00-8.00, which meets the percent weight limitation recited in claim 1 (see column 7, line 10 through column 8, lines 36, in particular.)

Accordingly, Guenin et al. teaches a fragrance composition having components that can be selected to provide the recited terpenoid weight percent, and that can be combined into cosmetic compositions to provide a fragrance and reduce odor.

Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the percent content of the fragrance in a cosmetic composition, and/or the percent content of terpenoid in the fragrance composition, in accordance with the guidance provided by Guenin et al, to provide a composition having a desired fragrance type and level. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Accordingly, one of ordinary skill in the art at the time the invention was made would have found it obvious to combine the fragrance composition of Guenin et al. into the skin care composition of Jokura et al. to devise the personal care composition of claim 1, because Jokura et al. teaches that the skin care composition comprising the dicarboxylic acid salt such as a salt of malonic acid can comprise conventional cosmetic additives such as a perfume, and Guenin et al. teaches a fragrance composition

(perfume) that can be combined into cosmetic compositions comprising a terpenoid as claimed. Thus, one of ordinary skill in the art would have been motivated to provide the terpenoid-containing fragrance composition of Guenin et al. into the skin care composition of Jokura et al. with the expectation of providing a skin care composition capable of moisturizing skin and having a desirable fragrance. Therefore, the composition of claim 1 is obvious over the teachings of Jokura et al. and Guenin et al.

Regarding claims 2-3 and 11, Jokura et al. teaches that the salt of the dicarboxylic acid can be formed by the addition of an alkali to for the aimed salt via neutralization in the system (see column 3, lines 45-50, in particular), which would form a mixture of half-neutralized and fully neutralized acid according to the amount of alkali added. Jokura et al. furthermore exemplifies compositions formed by addition of the acid and the fully neutralized salt (see table 2, in particular), which in solution would form an equilibrium amount of half neutralized and fully neutralized salt. Accordingly, it is considered that one of ordinary skill in the art at the time the invention was made would find it obvious to vary and/or optimize the amount of base/salt provided to achieve the ratios of half neutralized to fully neutralized dicarboxylic acid that provide optimum skin moisturizing effects without irritating skin, as taught by Jokura et al. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation."

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Regarding claims 4-5, Jokura et al. teaches that salts of the dicarboxylic acid can include alkali and alkali earth metals, such as sodium potassium calcium and magnesium, as in claim 4, and can also comprise alkanolamine salts such as triethanolamine, as in claim 5.

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Regarding claim 6, Guenin et al. teaches that fragrance composition can be combined into the composition in an amount of from 1.8 to 32.5% by weight, and teaches that the exemplary Deo-KeyTM fragrance compositions can combined in an amount of about 3% by weight (see column 8, line 63 through column 7, line 7, in particular), which meets the limitation of the fragrance percent content of from "about" 0.1 to "about" 5% with a terpenoid that is from "about" 0.1 to "about" 30% of the fragrance, as recited in the claim. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of fragrance and/or fragrance composition provided in the composition, according to the guidance provided by Jokura et al. and Guenin et al, to provide a composition having desired fragrance properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

Regarding claims 7-8, Guenin et al. teaches that the fragrance composition can be made by combining at least three components from a group of listed fragrances that

includes terpenoids such as d-limonene, citral and geraniol, and terpenoid containing fragrances such as Iso Methyl Cedryl Ketone A and Pelargonyl (see column 2, line 20 through column 3, line 35, in particular.) Geraniol is an acyclic terpenoid and limonene is a cyclic terpenoid, as recited in claim 7, and citral is an unsaturated aldehyde terpenoid, as recited in claim 8.

Regarding claims 9-10, Jokura et al. teaches that the dicarboxylic acid and dicarboxylic acid salt, such as malonic acid salt, have a percent by weight in the composition of from 0.01 to 20% (see column 3, lines 53-56, in particular), which meets the limitation of being from "about" 0.1 to "about" 15% by weight as recited in claim 9, and "about" 0.5 to "about" 10% by weight as recited in claim 10. Furthermore, it is considered that one of ordinary skill in the art at the time the invention was made would have found it obvious to vary and/or optimize the amount of malonic acid salt provided in the composition, according to the guidance provided by Jokura et al. and Guenin et al, to provide a composition having desired cosmetic properties. It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re

Accordingly, claims 1-11 are unpatentable over the teachings of Jokura et al. and Guenin et al.

(10) Response to Argument

Appellants argue that the claimed invention is not obvious over the combined teachings of Jokura et al. and Guenin. In particular, Appellants argue that: (1) the Jokura et al. and Guenin et al. references do not teach the stabilizing effect of malonate salts in preventing the oxidation of compounds such as terpenoids, and thus do not render the claimed invention obvious; (2) *in re Aller* has been improperly applied to reject the claims over Jokura et al. and Guenin et al; and (3) regarding dependent claims 2, 3 and 11, Jokura et al. and Guenin et al. do not specifically teach the composition having the ratio of half neutralized to fully neutralized acid as recited in the claims.

Appellants' arguments have not been found to be persuasive for the following reasons.

Regarding point (1), Appellants argue that the Jokura et al. reference is not concerned with the problem of fragrance component instability, or with the stability of terpenoids, and instead Appellants assert that Jokura et al. is only concerned with providing sufficient moisturizing effect while avoiding skin irritation. Appellants further note that Jokura et al's teaching of a "perfume" as a part of the composition is only mentioned once in the reference, and that Jokura et al. does not exemplify a composition containing a "perfume" in the Examples. Appellants further argue that

Guenin et al. does not disclose combating oxidative instability, and thus Appellants argue that it would require hindsight reconstruction to combine the teachings of the references.

The Examiner respectfully disagrees. In response to Appellants' argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

In response to Appellants' argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, Jokura et al. teaches that the cosmetic composition having the malonic acid salt can comprise conventional cosmetic additives such as perfume, whereas Guenin et al. teaches that

the terpenoids as claimed are known to be suitable for fragrance compositions (perfumes) that can be incorporated into cosmetic compositions. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to provide the terpenoid-containing fragrance composition of Guenin et al. into the skin care composition of Jokura et al. with the expectation of providing a skin care composition that is capable of moisturizing the skin, and that has a desired fragrance.

Furthermore, in response to Appellants argument that the references do not teach or suggest the oxidative stability of terpenoids when combined with malonates, it is noted that the fact that Appellants have recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Regarding point (2), Appellants argue that the Examiner's recitation of *In re Aller* does not apply to the instant claims because *In re Aller* was applied for a single reference against process claims disclosing slightly different process conditions from those in the single reference, whereas the instant invention is focused on a composition rather than a process, and the rejection is being made over two references instead of a single reference.

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The Examiner notes that *In re Aller* was cited in rejecting the specific amounts of fragrance and terpenoids provided in the composition, as recited in claim 6, and in rejecting the specific amounts of malonic acid salt provided in the composition, as recited in claims 9-10. In re Aller states that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.) In the instant case, Guenin et al. discloses general ranges of amounts of terpenoids and fragrance compositions that can be provided in a cosmetic composition, and Jokura et al. discloses general ranges of amounts of malonic acid salts that are provided in the cosmetic composition, as has been discussed above. Thus, it is considered that as Jokura et al. and Guenin et al. disclose the general conditions of the claim, i.e. general amounts of the components that can be provided in the cosmetic composition, it is considered that the optimum or workable ranges of the amounts of these component could be discovered by routine experimentation by one of ordinary skill in the art, in accordance with the teachings of *In re Aller*.

Regarding point (3), Appellants argue that Jokura et al. teaches a composition having a combination of the unneutralized acid and a partially neutralized acid, and argue that "the free acid can only co-exist with a partially neutralized salt because of pKa considerations" (page 9, second full paragraph of Appeal Brief.) Appellants further argue that, as Jokura et al. requires the presence of the free acid, "any neutralization

that attempts to maintain free acid will not achieve the presence of a di-neutralized salt form" (see page 10, second full paragraph of Appeal Brief.)

The Examiner notes that Jokura et al. teaches providing a dicarboxylic acid and a salt of the dicarboxylic acid (components B and C as taught in abstract), which dicarboxylic acid can be malonic acid (column 3, lines 30-35.) However, the Examiner disagrees with Appellants assertion that Jokura et al. only teaches the "free" and "partially neutralized" acid forms, and instead notes that Jokura et al. does not particularly specify whether the salt is in "partially" or "fully" neutralized form, i.e., whether the salt has the formula (I) or (II) as disclosed in paragraph 00011 of page 3 of the instant specification.

The Examiner agrees with Appellants that the distribution of "partially" and "fully" neutralized acid in the composition will be dependent upon pKa considerations. In particular, the acid/base equilibrium equation for a dicarboxylic acid such as malonic acid in aqueous solution, as known to those of ordinary skill in the art, is as follows:

$$K_{a1}$$
 K_{a2}
1) $HO_2CCH_2CO_2H \rightarrow HO_2CCH_2CO_2^{-1} + H^{+} \rightarrow O_2CCH_2CO_2^{2-} + 2H^{+}$
Formula (I) Formula (II)

where K_{a1} and K_{a2} are the equilibrium constant for each "neutralization" (acid equilibrium) reaction, and Formulas (I) and (II) represent the formulas recited for the

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"partially" and "fully neutralized" acids as disclosed in paragraph 00011 of page 3 of the instant specification.

Thus, the "free acid," "partially neutralized" acid (formula I), and "fully neutralized acid (formula II), exist in solution in equilibrium with one another, with the concentration of the different forms being governed by the individual K_a of each "neutralization" reaction. For example, as known to those of ordinary skill in the art, the equilibrium constant K_{a2} for the ratio of the concentration of the "fully neutralized" products (formula II) to concentration of the "partially neutralized" reactants (formula I) is expressed as:

2) K_{a2} = [concentration of products]/[concentration of reactants]

= $2[H^{+}][O_{2}CCH_{2}CO_{2}^{2-}]/[H+][HO_{2}CCH_{2}CO_{2}^{-}]$

= $[H^{\dagger}][O_2CCH_2CO_2^{2-}]/[HO_2CCH_2CO_2^{-1}]$

Accordingly, the relative concentrations of the products and reactants is dependent on the Ka of the reaction, in agreement with the argument set forth by Appellants (the $pK_a = -\log K_a$.)

Note that the counter ions X^+ as disclosed in paragraph 00011 of page 3 of the instant specification are left out of the equilibrium equation (1) according to the standard convention as known to those of ordinary skill in the art, because the counter ions are not reactants or products that participate in the acid base reaction. That is, the "partially

neutralized" salt form, as shown by formula (I) of Appellants is equivalent in solution to the singly deprotonated form (I) shown in equation (1) above (i.e. one acid moiety has been "neutralized"), and the "fully neutralized" salt as cited by Appellants is equivalent in solution to the doubly deprotonated form (II) shown in equation (1) above (i.e. two acid moieties having been "neutralized".)

Returning to equation (2) above for the reaction governed by K_{a2} , the Examiner notes that, because the equilibrium constant is a "constant" for a given reaction, the concentration of products and reactants will shift when the concentration of any of the products or reactants are changed in solution in order to achieve the equilibrium Ka value. This concept is familiar to students in high school and college freshman chemistry classes as Le Chatelier's Principle. In other words, adding reactants to the solution creates a ratio of [products]/[reactants] that is lower than the Ka at equilibrium, and thus the reaction will proceed in the forward direction to form more product, until a ratio of [products]/[reactants] that equals the equilibrium constant Ka is achieved. Similarly, increasing the concentration of any of the products, such as [H+] or [O₂CCH₂CO₂²⁻], creates a ratio of [products]/[reactants] that is too high, and causes the reaction to proceed in "reverse" to form more reactants, until the equilibrium ratio Ka of the products to the reactants is achieved. Thus, adding or removing amounts of the product [H+] to the solution results in the formation of more reactants, i.e. the partially neutralized salt, and effectively changes the ratio of partially to fully neutralized acid forms.

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The effect of changes in the concentration of [H+] on the equilibrium amounts of the products and reactant can also be seen by re-arranging equation (2) above:

(3)
$$K_{a2}/[H^{+}] = [O_{2}CCH_{2}CO_{2}^{2-}]/[HO_{2}CCH_{2}CO_{2}^{-}]$$

Note that the right hand side of the equation is equivalent to the ratio of fully neutralized: partially neutralized acid, the inverse of the ratio as is recited by Appellants in claims 2-3 and 11. Thus, as K_{a2} is a constant for the given acid, malonic acid, the ratio of partially neutralized acid to fully neutralized acid will be dependent upon the concentration of H+ in solution. In other words, the ratio of partially neutralized to fully neutralized acid is governed by the pH of the solution (pH = - log[H $^+$].) That is, solutions having the same pH should have the same or similar ratios of partially neutralized to fully neutralized salts.

The Examiner notes that Jokura et al. teaches that a desirable pH range is from 3 to 10 and preferably from 3 to 9, and exemplifies compositions having a pH of 4.1 (see column 3, lines 60-65 and Table 2). This is a pH range that is about the generally accepted pH of 7 (i.e. neutral pH) that is considered to be suitable for cosmetic products that are used for application to skin. The Examiner notes that Appellants' are claiming a "personal care composition", which is defined in the specification by Appellants as being, a composition that is "for topical application to human skin" (see page 5,

paragraph 00016, in particular.) Thus, absent evidence to the contrary, it is considered that the Appellants' personal care composition is also provided in a pH range about 7. such as in a range that is at least close to or even overlaps with the pH of from 3 to 10. as taught by Jokura et al.

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It is further noted that Jokura et al. also teaches that the salt form can be provided by either adding the salt during preparation, or by adding alkali (base) to form the salt via neutralization (thereby effectively decreasing $[H^{\dagger}]$ in equations (2) and (3) above) (see column 3, lines 45-50, in particular), and thus teaches means by which the pH, and the ratio of partially to neutralized acid forms, can be adjusted.

Thus, as Jokura et al. teaches a pH range that is at least close to and/or overlaps with that of the instantly claimed composition having the ratio of partially to fully neutralized salt, it is considered that the composition of Jokura et al. does indeed have an amount of "fully neutralized" acid salt form present in the solution, contrary to Appellants' assertion that the fully neutralized salt cannot exist with the free acid, because the existence of the fully neutralized form is dependent upon the pH value of the solution. Furthermore, it is considered that one of ordinary skill in the art would have found it obvious to vary and/or optimize the pH and/or the ratio of salt form to free acid form as taught by Jokura et al. (column 3, lines 50-65) and thus simultaneously vary and/or optimize the ratio of partially neutralized to fully neutralized salt, to achieve a composition that imparts the skin benefits as taught by Jokura et al. Accordingly, the

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malonic acid salt having the ratio of partially neutralized to fully neutralized salt forms is

considered to be obvious over the teachings of Jokura et al.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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Abigail M. Cotton Examiner Art Unit 1617

May 10, 2006

Conferees:

Sreeni Padmanabhan Shengjun Wang

> SREENI PADMANABHAN SUPERVISORY PATENT EXAMINER